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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** | |
| **Mastectomy** |  |  |  |  |  |  | |
| ***Current Review*** |  |  |  |  |  |  | |
| Borreani et al., 2014187  Fair | Psychological  QOL  Body Image | To describe the impact of preventive options on the psychological condition of cancer-unaffected *BRCA1* or *BRCA2* carriers. | Prospective cohort | Eligible: 101\*  Enrolled: 27  Analzyed: 27 | Italy | Cancer centers |
| den Heijer et al., 2012192  NA  Drawn from same population as Bresser, 2007191 | Psychological Body image | To explore the course of psychological distress and body image at long-term followup (6 to 9 years) after prophylactic mastectomy and breast reconstruction (PM/BR) in women at risk for hereditary breast cancer, and to identify pre-PM risk factors for poor body image on the long-term. | Before and after | Eligible: Not reported  Enrolled: 36  Analyzed: 36 | The Netherlands | Family Cancer Clinica of the ErasmusMC-Daniel den Hoed Cancer Center | |
| Gopie et al., 2013196  NA | Sexual functioning  Body image  Psychological | To explore the course of body image, and of satisfaction with the sexual and partner relationship, as well as of cancer distress, and health related quality of life in women opting for BPM with immediate breast reconstruction. | Before and after | Eligible: 73  Enrolled: 50  Analyzed: 50 | The Netherlands | Academic and regional hospitals | |
| Isern et al., 2008199  Fair | Psychological | To investigate long-term results of aesthetic outcome, patient satisfaction, health-related quality of life and complication rates among women undergoing prophylactic mastectomy and immediate breast reconstruction in a single institution. | Retrospective cohort | Eligible: Not reported  Enrolled: 28  Analyzed: 28 | Sweden | Malmo University Hospital | |

| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
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| **Mastectomy** |  |  |  |
| ***Current Review*** |  |  |  |
| Borreani et al., 2014187  Fair | Mean age, years: 39.4 (SD 9) | Inclusion: Women who received a positive result of a deleterious mutations in *BRCA1* and/or *BRCA2,* seen at 1 of 3 cancer centers  Exclusion: The study included women with cancer, but reported results separately, so we did not include women with cancer. | *BRCA 1/2* mutation carriers |
| den Heijer et al., 2012192  NA  Drawn from same population as Bresser, 2007191 | Mean age, years: 40.1 (7.7)  Breast cancer history: 33% (12/36)  Ovarian cancer history: 3% (1/36)  P(B)SO: 47% (17/36) | Inclusion: Women who had participated in PREVOM-B  (Bresser, 2007)227 had not developed a new cancer or recurrent cancer since enrollment in the PREVOM-B study, and still were in followup at the family cancer clinic.  Exclusion: Not reported | All women came from families with an apparent autosomal dominant transmission pattern, and therefore had an associated elevated risk of breast/ovarian cancer. |
| Gopie et al., 2013196  NA | Mean age at time of BPM, years: 37.1 (SD 10.2)  PBSO: 22.9% (11/50) | Inclusion: Healthy, unaffected women at significantly increased risk of breast cancer due to a BRCA mutation or relevant family history who had opted for BPM with immediate breast reconstruction  Exclusion: Suspicion of breast cancer in the planning towards BPM and a detection of breast cancer in the followup, and not being able to understand and speak the Dutch language sufficiently | Unclear, had to either have *BRCA1/2* mutation or relevant family history |
| Isern et al., 2008199  Fair | Median age, years: 38 (range: 25 to 51)  Median age at followup, years: 40 | Inclusion: Otherwise healthy women with an increased risk of developing breast cancer who underwent prophylactic mastectomy and immediate reconstruction.  Exclusion: Not reported | Mutation carriers or belonging to families with a dominant inheritance of a greatly increased risk of breast cancer. |

| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
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| **Mastectomy** |  |  |  |  |
| ***Current Review*** |  |  |  |  |
| Borreani et al., 2014187  Fair | 74.1% (20/27) *BRCAI*  25.9% (7/27) *BRCA2* | Hospital Anxiety and Depression Scale (HADS, both anxiety and depression scales 0 to 21)  Breast Cancer Worry Scale (scale 6 to 24)  Medical Outcomes Study Short Form Health Survey 12-item (MOS SF-12, scale 0 to 100)  Adapted Digital Body Photo Test (scale unclear)  Satisfaction measured with three questions not described | A) Surveillance  B) Surgery (PBM and/or PBSO) | November 2008 to June 2010  15 months |
| den Heijer et al., 2012192  NA  Drawn from same population as Bresser, 2007191 | 75% (27/36) *BRCA 1/2*  mutation carriers | Body Image Scale (BIS, general body image scale 5 to 25 and breast related body image scale 2 to 10)  Hospital Anxiety and Depression Scale (HADS, both anxiety and depression scales 0 to 21)  Impact of Events Scale (IES, intrusion scale 0 to 35  and avoidance scale 0 to 40) | RRM with reconstruction | August 1999 to February 2003  Duration: 9 years |
| Gopie et al., 2013196  NA | 88% (44/50) *BRCA 1/2* mutation carriers | Body Image Scale (BIS, scale 1 to 5)  Dutch Relationship Questionnaire, Nederlandse Relatie Vragenlijst (NRV, sexuality subscale 0 to 12)  Impact of Events Scale (IES, scale 0 to 75)  Dutch version of the 36-item Short-Form Health Survey (SF-36, Physical Component Summary [PCS] and Mental Component Summary [MCS] subscales 0 to 100) | RRM with reconstruction | December 2007 to May 2010  Mean duration 21.7 months (range: 12 to 35 months) |
| Isern et al., 2008199  Fair | Not reported for women without cancer only | Hospital Anxiety and Depression Scale (HADS, each subscale 0 to 15)  Short Form 36 Health Survey Questionnaire (SF-36, scale 0 to 100) | 1. RRM with reconstruction 2. Age-matched reference group who did not undergo RRM | 1995 to November 2003  Duration: NR |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
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| **Mastectomy** |  |  |  |
| ***Current Review*** |  |  |  |
| Borreani et al., 2014187  Fair | **Surveillance (n=19) vs. Surgery (n=8)**  Mean HADS-anxiety score (difference from baseline): 7.21 (-0.05, 95% CI -1.09 to 0.98) vs. 6.38 (-0.12, 95% CI -2.04 to 1.79)  Mean HADS-depression score (difference from baseline): 5.37 (0.37, 95% CI -0.91 to 1.65) vs. 4.5 (0.00, 95% CI -2.75 to 2.75)  Mean breast cancer worry scale score (difference from baseline): 5.47 (-0.11, 95% CI -0.70 to 0.49) vs. 4.75 (-2.75, 95% CI -5.15 to -0.35)  Mean ovarian cancer worry scale score (difference from baseline): 4.79 (-0.16, 95% CI -0.83 to 0.51) vs. 4.13 (-2.38, 95% CI -5.20 to 0.45)  Mean physical QOL score (difference from baseline): 53.66 (-0.69, 95% CI -1.96 to 0.60) vs. 52.43 (-2.80, 95% CI -6.42 to 0.82)  Mean psychological QOL score (difference from baseline): 47.17 (0.20, 95% CI -4.41 to 4.81) vs. 6.14 (-0.21, 95% CI -2.28 to 1.85)  Mean overall aesthetic satisfaction score (difference from baseline): 6.99 (0.04, 95% CI -0.28 to 0.37) vs. 6.48 (-0.29, 95% CI -1.24 to 0.66)  Mean breast aesthetic satisfaction score (difference from baseline): 6.88 (-0.03, 95% CI -1.04 to 0.97) vs. 6.14 (-0.21, 95% CI -2.28 to 1.85)  Mean choice satisfaction: 3.84 vs. 4.38 | Women who chose surveillance and surgery had average levels of anxiety and depression and neither group was above the 8 point threshold. Breast cancer worry decreased in both groups over time, but was only statistically significant for women who chose surgery. QOL decreased in both groups, but was not statistically significant. Women were satisfied with their overall aesthetic and breast aesthetic. | Italian Cancer League |
| den Heijer et al., 2012192  NA  Drawn from same population as Bresser, 2007191 | **2-4 weeks before surgery (T0) vs. 6 months after (T1) vs. 6-9 years after surgery (T2)**  Mean general distress: 9.91 vs. 7.45 vs. 6.58, p=0.03 for T0 vs. T1 and p=0.01 for T1 vs. T2  Mean breast cancer specific distress: 22.7 vs. 12.9 vs. 6.1, p=0.01 for both T0 vs. T1 and T1 vs.  T2  Mean general body image: 10.7 vs. 12.4 vs. 11.7, p=0.01 for T0 vs. T1 and NS for T1 vs. T2  Mean breast related body image: 5.0 vs. 6.7 vs. 5.9, p=0.01 for T0 vs. T1 and p=0.03 for T1 vs.  T2 | Psychological distress decreases after RRSO with breast reconstruction. | Grant from the Dutch Cancer Society (KWF EMC 2006-3468) |
| Gopie et al., 2013196  NA | **Before BPM (T0) vs. 6 months after (T1) vs. 12 months after (T2)**  Mean BIS: 3.8 vs. 3.3 vs. 3.5, p<0.001 for T0 vs. T1 and p=0.06 for T0 vs. T2  Mean NRV: 9.0 vs. 8.5 vs. 8.0, p=0.07 for T0 vs. T1 and p=0.06 for T0 vs. T2  Mean IES: 23 vs. 12 vs. 13, p<0.001 for T0 vs. T1 and T0 vs. T2  Mean SF-36 PCS: 55 vs. 48 vs. 53, p<0.001 for T0 vs. T1 and p=0.37 for T0 vs. T2  Mean SF-36 MCS: 48 vs. 51 vs. 50, p=0.02 for T0 vs. T1 and p=0.19 for T0 vs. T2 | BPM with immediate breast reconstruction was associated with adverse impact on body image, but satisfaction with sexual relationship did not significantly change over time. | Dutch Cancer Society (UL 2007-3726) |
| Isern et al., 2008199  Fair | Women without previous breast cancer scored higher on all aspects of the SF-36 vs. the reference group, but was only statistically significant for physical functioning (p<0.0001), vitality (p=0.042), and social functioning (p=0.007).  No significant differences found between *BRCA 1/2* mutation carriers vs. noncarriers or between women with or without previous cancer on HADS, actual data not provided. | SF-36 scores were high in women after surgery, suggesting PM and reconstruction had no negative effect on both physical and psychological issues. Also, anxiety and depression scores were not significant on HADS, suggesting no increase in anxiety or depression among patients. | Not reported |

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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Mastectomy** |  |  |  |  |  |  |
| ***Current Review*** |  |  |  |  |  |  |
| Stefanek et al., 1995211  Poor | Psychological | To examine the factors related to making a decision about prophylactic mastectomy among women attending a high-risk clinic for breast cancer who chose prophylactic mastectomy compared with women who chose breast surveillance without surgery. | Cohort | Eligible: Not reported  Enrolled: 164  Analyzed: 164  (14 cases; 150 controls) | U.S. | Breast Surveillance Services of the Johns Hopkins Oncology Center |
| ***2013 Review*** |  |  |  |  |  |  |
| Brandberg et al., 2008190  Brandberg et al., 2012189  NA | Sexual functioning  Psychological | To prospectively evaluate body image, sexuality, emotional reactions, and quality of life in a sample of women having increased risk for breast cancer before RRM, and 6 months and 1 year after. | Before and after | Eligible: Not reported  Enrolled: 90  Analyzed: 65 | Sweden | Karolinska University Hospital |

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| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
| **Mastectomy** |  |  |  |
| ***Current Review*** |  |  |  |
| Stefanek et al., 1995211  Poor | Mean age, years: 37.8 (SD 9, range 18 to 70) | Inclusion: Women with ≥1 first-degree relative diagnosed with breast cancer during the period of January 1988 to November 1992  Exclusion: Not reported | Unclear, had ≥1 first-degree relative diagnosed with breast cancer |
| ***2013 Review*** |  |  |  |
| Brandberg et al., 2008190  Brandberg et al., 2012189  NA | **Age, years**  20-29: 8% (7/90)  30-39: 37% (33/90)  40-49: 39% (35/90)  50-59: 14% (13/90)  60-69: 2% (2/90) | Inclusion: Women how had RRM including reconstruction.  Exclusion: Women with a breast cancer diagnosis. | Lifetime risk definition not described  50% lifetime risk: 28.9% (26/90)  25% lifetime risk: 8.9% (8/90) |

| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
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| **Mastectomy** |  |  |  |  |
| ***Current Review*** |  |  |  |  |
| Stefanek et al., 1995211  Poor | Not reported | Center for Epidemiologic Studies-Depression (CES-D, scale 0 to 60)  Questionnaire assessing satisfaction with PM (5-point Likert type scale, 1=not at all satisfied; 5= very much satisfied)  Rating scale of worry (7-items on 7-point Likert type scale; 1=not a problem at all; 7=severe problem) | 1. PM 2. Surveillance only | January 1988 to November 1992  Mean 9.4 months (SD 6.8, range 6 to 30) |
| ***2013 Review*** |  |  |  |  |
| Brandberg et al., 2008190  Brandberg et al., 2012189  NA | 41.1% (37/90) *BRCA* 1  14.4% (13/90) *BRCA* 2  2.2% (2/90) unknown mutation | Body Image Scale (BIS, scale 0 to 30)  Hospital Anxiety and Depression Scale (HAD, subscales 0 to 21)  Impact on areas of life measures  Sexuality Activity Questionnaire (SAQ, pleasure subscale 0 to 18, discomfort subscale 0 to 6, and habit subscale 0 to 3)  Swedish Short Term-36 Health Survey (SF-36, subscales 0 to 100) | RRM with reconstruction | October 1997 to December 2005  1 year |

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| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **Mastectomy** |  |  |  |
| ***Current Review*** |  |  |  |
| Stefanek et al., 1995211  Poor | **A vs. B**  Worry of at least moderate problem: 86% (12/14) vs. 60% (90/150), p<0.001  **Satisfaction with PM (n=14)**  Very much: 71% (10/14)  Little to somewhat: 14% (2/14) Not at all: 14% (2/14)  None of the patients had CES-D scores indicative of clinical depression. | Women were satisfied with their decision to undergo surgery, but they did have higher levels of worry than women undergoing suerveillance, which may be why they chose to undergo surgery. | Not reported |
| ***2013 Review*** |  |  |  |
| Brandberg et al., 2008190  Brandberg et al., 2012189  NA | **Mean scales (SE), before RRM vs. 6 months after RRM vs. 1 year after RRM**  HAD-A: 5.59 (0.55) vs. 3.80 (0.55) vs. 3.83 (0.52); p=0.0004  HAD-D: 2.53 (0.39) vs. 1.93 (0.31) vs. 1.98 (0.36); p=NS  SAQ, pleasure subscale: 12.82 (0.62) vs. 12.21 (0.66) vs. 11.18 (0.56); p=0.005  SAQ, discomfort subscale: 0.56 (0.15) vs. 0.53 (0.20) vs. 0.81 (0.19); p=NS  SAQ, habit subscale: 0.94 (0.06) vs. 0.82 (0.08) vs. 0.82 (0.08); p=NS  Bodily pain as reported by SF-36: 81.0 (2.98) vs. 80.7 (2.84) vs. 82.6 (3.29); p=NS  NS difference over time on any portion of Impact on areas of life measures, any portion of BIS, and any subscales of SF-36. | Anxiety decreased after surgery, while sexual pleasure increased. All other measures did not change over time. | Swedish Cancer  Society, the Swedish Association for Cancer and Traffic Victims, and the Stockholm County Council |

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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Mastectomy** |  |  |  |  |  |  |
| ***2013 Review*** |  |  |  |  |  |  |
| Gahm et al., 2010195  NA | Sexual functioning  QOL  Pain | To analyze the physical effects and to report effects on sexual functioning and health-related quality of life at least 2 years after RRM. | Cross-sectional | Eligible: Not reported  Enrolled: 1784 (59 with RRM and 1725 included as reference sample) | Sweden | Karolinska University Hospital |

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| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Gahm et al., 2010195  NA | Mean age, years: 40 (range 25 to 65) | Inclusion: Women with increased risk for breast cancer, who had undergone RRM and immediate breast reconstruction  Exclusion: Personal history of breast cancer | Not reported |

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| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
| **Mastectomy** |  |  |  |  |
| ***2013 Review*** |  |  |  |  |
| Gahm et al., 2010195  NA | Not reported | Decision Regret Scale (DRS, scale NR)  Pain and discomfort questionnaire (subscales 1 to 7)  Sexuality questionnaire  Swedish Short Term-36 Health Survey (SF-36, subscales 0 to 100) | 1. RRM with reconstruction 2. Reference comparison group who did not undergo RRM | 2004 to 2006  Mean followup, months: 29 (range 24 to 49) |

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| **Author, year**  **Quality** | ***Results*** | ***Conclusions*** | ***Funding source*** |
| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Gahm et al., 2010195  NA | **Mean SF-36 subscales (estimated from graph), A vs. B**  Physical functioning: 94 vs. 89; p=NS  Role functioning: 86 vs. 85; p=NS  Bodily pain: 87 vs. 72; p=0.002  General health: 79 vs. 77; p=NS  Vitality: 68 vs. 68; p=NS  Social functioning: 90 vs. 89; p=NS  Role emotional: 80 vs. 85; p=NS  Mental health: 80 vs. 80; p=NS  **Pain and discomfort questionnaire responses after RRM**  69% (38/55) pain in breasts  36% (20/55) pain affected sleep  22% (12/55) pain affected daily activities  71% (39/55) discomfort in breasts  87% (48/55) pain or discomfort in breasts  No association between pain and age (OR 0.99, p=0.771); pain and complication (OR 0.60, p=0.538); or pain and re-operation (OR 3.72, p=0.110)  Pain or discomfort not related with negative effects in sexual outcomes (p>0.05 for both)  **Post operative complications**  18.6% (11/59) had infections  5.1% (3/59) required implant extraction  6.8% (4/59) had hematoma  3.4% (2/59) required acute operative evacuation  3.4% (2/59) had revision of flap necrosis  59% (35/59) had corrective surgical procedures  41% (24/59) had procedure involving implant pockets | Women who underwent RRM had less bodily pain than the reference group, but no other differences on the SF=36.  Most women who underwent RRM experienced pain, discomfort, and decrease in sexual enjoyment, attractiveness, and enjoyment. However, almost all women felt the choice was a good one and would make the same decision. | None |

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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Mastectomy** |  |  |  |  |  |  |
| ***2013 Review*** |  |  |  |  |  |  |
| Metcalfe et al., 2004205  NA | Sexual functioning  Psychological | To assess psychosocial functioning in a population-based series of women who have previously undergone RRM in a specified time period. | Case-series | Eligible: 122  Enrolled: 75  Analyzed: 60 | Canada | Ontario hospitals in The Central East Health Information Partnership |

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| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Metcalfe et al., 2004205  NA | Mean age at time of surgery, years: 43.5 (SD 7.8)  Mean age at time of questionnaire, years: 47.8 (SD 8.6) | Inclusion: Women who underwent a RRM at an Ontario hospital and returned the questionnaire  Exclusion: Prior or current diagnosis of invasive or in situ breast cancer | Strong family history: had either one 1st degree relative or two 2nd degree relatives with any of the following: 1) breast cancer diagnosed <50 years; 2) ovarian cancer; or 3) male breast cancer (55.0% of population, also did not have genetic testing done) Limited family history: none of the above (23.3% of population, also did not have genetic testing done) |

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| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
| **Mastectomy** |  |  |  |  |
| ***2013 Review*** |  |  |  |  |
| Metcalfe et al., 2004205  NA | 21.7% had *BRCA1/2* mutation | Body Image after Breast Cancer (BIBC, each subscale 1 to 5)  Brief Symptom Inventory (BSI, scale 0 to 100)  Impact of Events Scale (IES, IES-I subscale 0 to 35 and IES-A subscale 0 to 40)  Sexual activity questionnaire (pleasure subscale 0 to 18, discomfort subscale 0 to 6, habit subscale 0 to 3) | RRM  88.3% (53/60) total  11.7% (7/60) subcutaneous | January 1991 to June 2000  Mean time between surgery and questionnaire, months: 52.2 (SD 32.3) |

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| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Metcalfe et al., 2004205  NA | 97% were satisfied or extremely satisfied with decision to undergo RRM  **Mean scales (SD) for whole group after RRM**  IES-I: 8.44 (8.11); 7.0% (4/57) scored above clinical cut-off, of these all (100%) had a strong family history of breast cancer and 75% (3/4) had a mother who died from breast cancer  IES-A: 8.79 (8.53); 8.8% (5/57) scored above clinical cut-off, 60% (3/5) had a strong family  history of breast cancer, 20% (1/5) had a BRCA mutation, and 20% (1/5) had a mother who died of breast cancer  Sexual activity, pleasure: 12.25 (4.72)  Sexual activity, discomfort: 1.97 (2.13)  Sexual activity, habit: 1.22 (0.66)  BIBC, vulnerability: 2.43 (0.81)  BIBC, body concerns: 3.09 (0.99)  BIBC, body stigma: 2.33 (0.89)  BIBC, transparency: 2.19 (0.79)  **Mean scales (SD), age <50 years vs. >50 years**  IES-I: 9.07 (8.57) vs. 6.31 (6.10); p=NS  IES-A: 8.61 (9.03) vs. 9.38 (6.85); p=NS  Sexual activity, pleasure: 12.75 (4.70) vs. 10.25 (4.56); p=NS  Sexual activity, discomfort: 1.78 (2.12) vs. 2.88 (2.03); p=NS  Sexual activity, habit: 1.18 (0.64) vs. 1.42 (0.79); p=NS  BIBC, vulnerability: 2.38 (0.80) vs. 2.60 (0.87); p=NS  BIBC, body concerns: 3.12 (1.03) vs. 2.99 (0.86); p=NS  BIBC, body stigma: 2.27 (0.91) vs. 2.52 (0.81); p=NS  BIBC, transparency: 2.26 (0.86) vs. 1.97 (0.46); p=NS  **Post surgical symptoms**  64.4% (38) of women reported post surgical symptoms:  Numbness (27), pain (7), tingling (7), infection (7), swelling (2), breast hardness (2), bleeding (1), organizing hematoma (1), failed reconstruction (1), breathing complications (1), thrombosis (1), pulmonary embolism (1)  18 women reported only 1 symptoms, 15 women reported having had 2 symptoms and 5 women reported having 3 symptoms as a result of surgery. No difference in reporting of post- surgical symptoms based on time elapsed since mastectomy. | Most women were happy with their decision to undergo RRM. For most women the surgery did not cause high levels of distress and there was no correlation with age. | Not reported |

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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Mastectomy** |  |  |  |  |  |  |
| ***2013 Review*** |  |  |  |  |  |  |
| Wasteson et al., 2011212  NA | Risk perception  Psychological | To evaluate the long-term physical and psychological consequences of RRM in after 10 years. | Case-series | Eligible: Not reported  Enrolled: 15  Analyzed: 13 | Sweden | Women at Karolinska University Hospital enrolled in retrospective study. |
| **Mastectomy vs. Oophorectomy** | | | | | | |
| ***Current Review*** |  |  |  |  |  |  |
| Bresser et al., 2007191  Fair | Psychological | To examine whether PM and/or PSO would cause major psychological distress. | Retrospective cohort | Eligible: Not reported  Enrolled: 78  Analyzed: 78 | The Netherlands | Family Cancer Clinica of the ErasmusMC-Daniel den Hoed Cancer Center  *Reference group was from MRISC study* |
| Michelsen et al., 2009206  NA | QOL  Fatigue | To investigate quality of life (QoL) and fatigue in a sample of women who had RRSO for increase cancer risk and to compare the findings with those of age-matched controls from the general population. | Cross-sectional | Eligible: Not reported  Enrolled: 301  Analyzed: 205 (without cancer) | Norway | Stavanger University Hospital, Ulleval University Hospital, or the Norwegian Radium Hospital |

| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
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| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Wasteson et al., 2011212  NA | Mean age, years: 45 (range 40 to 57) | Inclusion: Women enrolled in previous retrospective study of RRM with reconstruction, agreed to participate 10 years later  Exclusion: Not reported | Either BRCApositive or 25% to 40% life-time risk of breast cancer according to Mendelian laws and the estimated penetrance of the *BRCA1* and *BRCA2* mutations, or to Claus tables |
| **Mastectomy vs. Oophorectomy** | |  |  |
| ***Current Review*** |  |  |  |
| Bresser et al., 2007191  Fair | Mean age, years: 43 (SD 8.6)  History of breast cancer: 35% (27/78)  History of ovarian cancer: 1% (1/78) | Inclusion: High-risk women who decided to undergo PM and/or PSO as risk reducing procedure, with no signs or suspicion of breast/ovarian cancer should be present in unaffected women at pre-surgical examination (physical and imaging examination, plus CA-125 analysis) performed within 3 months prior to surgery. Women with a history of breast/ovarian cancer were to have no signs of recurrent disease or a new primary breast or ovarian cancer after physical and imaging/dissemination examination consisting of mammography, gynecological ultrasound, chest X-ray, ultrasound liver, bone scan, liver- function tests, and CA-125/CA-153 analysis also performed within 3 months prior to surgery.  *Reference group:* Women with comparable increased risks, but opting for regular screening (MRISC study).  Exclusion: Not reported | All women came from families with an apparent autosomal dominant transmission pattern, and therefore had an associated elevated risk of breast/ovarian cancer. |
| Michelsen et al., 2009206  NA | Not reported separately for women without breast cancer | Inclusion: Women who had undergone RRSO for being either carriers of BRCA 1/2 mutations or belonging to hereditary breast-ovarian cancer families without identified mutation based on genetic counseling and/or testing at the Norwegian Radium Hospital  Reference group: Women drawn from public address lists, age- representative sample of the Norwegian female population aged 20 to 79 years  Exclusion: Not reported | Unclear, had to either have BRCA 1/2 mutation or belonging to hereditary breast-ovarian cancer families without identified mutation |

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| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
| **Mastectomy** |  |  |  |  |
| ***2013 Review*** |  |  |  |  |
| Wasteson et al., 2011212  NA | 23.1% (3/13) BRCA positive by 10 year followup | Semi-structured interviews focused on experiences related to RRM with reconstruction | RRM with reconstruction | Years: not reported  Median 10 years (range 9 to 12) |
| **Mastectomy vs. Oophorectomy** | |  |  |  |
| ***Current Review*** |  |  |  |  |
| Bresser et al., 2007191  Fair | 69% (54/78) *BRCA1/2* mutation carriers | Hospital Anxiety and Depression Scale (HADS, both anxiety and depression scales 0 to 21)  Impact of Events Scale (IES, intrusion scale 0 to 35 and avoidance scale 0 to 40) | 1. PM (n=52) 2. PSO (n=26) | August 1999 to February 2003  1 year |
| Michelsen et al., 2009206  NA | 19% (56/301) BRCA1/2 mutation carriers, of whole population | European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQ-C30, each subscale 0 to 100)  Fatigue Questionnaire (FQ, physical and mental subscales and total score scale )  Hospital Anxiety and Depression Scale (HADS, both anxiety and depression scales 0 to 21) | RRSO | 1991 to 2006  Mean 5.3 years (SD 3.1) |

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| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **Mastectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Wasteson et al., 2011212  NA | **Affects 10 years after RRM with reconstruction**  61.5% (8/13) stated family life unchanged  30.8% (4/13) stated positive affect on family life  38.5% (5/13) stated negative affect on relationship with spouse (due to decreased sensation and changed body appearance)  76.9% (10/13) considered cosmetic results positive  90.9% (10/11) had discussed breast cancer risk with daughters | Most women stated positive affects 10 years after RRM with reconstruction. | Not reported |
| **Mastectomy vs. Oophorectomy** | |  |  |
| ***Current Review*** |  |  |  |
| Bresser et al., 2007191  Fair | **A vs. B on HADS anxiety scale (SD)**  Mean at 6 months after surgery: 4.6 (3.8) vs. 5.3 (3.7)  Mean at 12 months after surgery: 4.5 (3.1) vs. 5.1 (3.5), p=0.003 for time X intervention  Scored above cutoff at 6 months: 18% (9/52) vs. 19% (5/26)  Scored above cutoff at 12 months: 10% (5/52) vs. 19% (5/26)  **A vs. B on HADS depression scale (SD)**  Mean at 6 months after surgery: 3.0 (3.1) vs. 3.0 (2.6), NS  Mean at 12 months after surgery: 3.3 (2.9) vs. 3.0 (2.3), NS  Scored above cutoff at 6 months: 8% (4/52) vs. 4% (1/26)  Scored above cutoff at 12 months: 6% (3/52) vs. 4% (1/26)  **A vs. B on IES intrusion scale (SD)**  Mean at 6 months after surgery: 6.7 (7.1) vs. 6.6 (6.4)  Mean at 12 months after surgery: 7.2 (7.2) vs. 7.9 (7.2), NS  Scored above cutoff at 6 months: 22% (11/52) vs. 15% (4/26)  Scored above cutoff at 12 months: 19% (10/52) vs. 27% (7/26)  **A vs. B on IES avoidance scale (SD)**  Mean at 6 months after surgery: 7.2 (8.4) vs. 8.0 (8.8)  Mean at 12 months after surgery: 5.6 (7.0) vs. 6.7 (7.2), p=0.002 for time X intervention  Scored above cutoff at 6 months: 20% (10/52) vs. 41% (11/26)  Scored above cutoff at 12 months: 20% (10/52) vs. 22% (6/26) | Most women who undergo PM and/or PSO do not develop major emotional distress. | Grant from the Netherlands' Organization for Health Research and Development (OG98-003) |
| Michelsen et al., 2009206  NA | **Mean score (SD) for cancer negative women who underwent RRSO**  EORTC QLQ-C30 physical functioning subscale: 90.0 (15.6)  EORTC QLQ-C30 role functioning subscale: 86.5 (24.6)  EORTC QLQ-C30 emotional functioning subscale: 83.3 (17.6)  EORTC QLQ-C30 cognitive functioning subscale: 86.0 (16.7)  EORTC QLQ-C30 social functioning subscale: 86.1 (20.9)  EORTC QLQ-C30 overall QOL: 75.5 (22.0)  FQ-physical fatigue subscale: 7.9 (2.9)  FQ-mental fatigue subscale: 4.4 (1.2)  FQ-total fatigue: 12.3 (3.7), 13% (27/205) diagnosed with chronic fatigue | Women unaffected by cancer had high levels of QOL and fatigue. | Not reported |

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| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Oophorectomy** |  |  |  |  |  |  |
| ***2013 Review*** |  |  |  |  |  |  |
| Finch et al., 2011194  NA | Sexual functioning | To examine the impact of RRSO on menopausal symptoms and sexual functioning among women who carry a *BRCA 1/2* mutation. | Case-series | Eligible: Not reported  Enrolled: 67 | Canada | University Health Network |

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| **Author, year**  **Quality** | **Demographics** | **Inclusion and Exclusion criteria** | **Risk level definition** |
| **Oophorectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Finch et al., 2011194  NA | Not reported separately for women without breast cancer | Inclusion: Women aged 30 to 70 years at time of surgery, who underwent RRSO  Exclusion: Diagnosed with occult cancer at surgery or with breast cancer during the 1 year followup period | High-risk due to positive genetic mutation |

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| **Author, year**  **Quality** | **Mutation status** | **Measures** | **Interventions** | **Duration of followup** |
| **Oophorectomy** |  |  |  |  |
| ***2013 Review*** |  |  |  |  |
| Finch et al., 2011194  NA | *BRCA1* or *BRCA2* positive | Menopause-Specific Quality of Life-Intervention (MENQOL, scale NR)  Sexual Activity Questionnaire (scale NR) | RRSO | October 2002 to June 2008  1 year |

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| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **Oophorectomy** |  |  |  |
| ***2013 Review*** |  |  |  |
| Finch et al., 2011194  NA | Women experienced a significant worsening of vasomotor symptoms (p<0.01) and a decrease in sexual function (p<0.05) | Women had worse vasomotor symptoms and decrease in sexual functioning. | Toronto Fashion Show, the Kristi Piia Callum Memorial Fellowship in Ovarian Cancer Research, and the University of Toronto Open Fellowship |

\*The study only reported the overall number enrolled, so this number includes women with cancer and those without cancer

**Abbreviations:** BIBC=body Image after Breast Cancer; BIS=body Image Scale; BPM=bilateral prophylactic mastectomy; BR=breast reconstruction; BRCA=breast cancer susceptibility gene; BSI=Brief Symptom Inventory; CES-D=Center for Epidemiological Studies Depression scale; DRS=Decision Regret Scale; EORTC QLC-C30=European Organization for Research and

Treatment of Cancer Quality of Life Questionnaire-C30; FQ=Fatigue Questionnaire; HADS=Hospital Anxiety and Depression Scale; IES=Impact of Events Scale; MCS=Mental Component Summary; MENQOL=Menopause-Specific Quality of Life-Intervention; MRISC-B study=Magnetic Resonance Imaging Screening for Breast Cancer study; NA=not applicable; NR=not reported; NRV=Nederlandse Relatie Vragenlijst; NS=not significant; OR=odds ratio; PBSO=prophylactic bilateral salpingo-oophorectomy; PCS=Physical Component Summary; PM=prophylactic mastectomy; PREVOM-B=study on the psychological impact of prophylactic surgery; PSO=prophylactic salpingo-oophorectomy; QOL=quality of life; RRM=risk-reducing mastectomy; RRSO=risk-reducing salpingo-oophorectomy; SAQ=Sexual Activity Questionnaire; SD=standard deviation; SE=standard error; SF-36=Short Form 36 Health Survey; U.S.=United States